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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,015	02/17/2004	Guy Bemis	VPI/03-05 US	2429
27916 7590 01/06/2010 VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242				
EXAMINER ZHOU, SHUBO				
ART UNIT 1631		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,015

Applicant(s)

BEMIS ET AL.

Examiner

SHUBO (Joe) ZHOU

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed 9/25/09 is acknowledged and entered.

Claims 1-34 are currently pending, and claims 1-31 and 34 are under examination. Claims 32-33 have been previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections-35 USC § 101

The rejection of claims 1-31 and 34 under 35 U.S.C. 101 is withdrawn in view of applicant's argument in view of *In re Bilski*, which is found persuasive.

Claim Rejections-35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-31 and 34 under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment and applicant's argument filed 9/25/09.

The following rejection is necessitated by applicant's amendment filed 9/25/09.

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Claims 1-31 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 30, 31 and 34 are amended to recite "the comparison macromolecule has structural features homologous to the target macromolecule of 20% or greater nucleic acid and/or amino acid homology." The limitation is indefinite because it's unclear whether it means that the comparison macromolecule and the target macromolecule as a whole share 20% or greater nucleic acid and/or amino acid homology or certain "structural features" thereof share 20% or greater nucleic acid and/or amino acid homology.

Claim 9 is amended to recite the phrase "connected to the cyclic and acyclic portions." While there is antecedent basis for cyclic portions, there's no sufficient antecedent basis for acyclic portions.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 is amended to recite that “the structural model of the query ligand is based on data from X-ray crystallography or NMR spectroscopy and the structural model of the target macromolecule is based on data from X-ray crystallography” in step (a). Applicant did not specifically point out support in the specification for the limitation. A review of the specification reveals that while the specification generally mentions data of molecules from X-ray crystallography or NMR, there's no specific description that could land support for the added limitation, i.e. “the structural model of the query ligand is based on data from X-ray crystallography or NMR spectroscopy and the structural model of the target macromolecule is based on data from X-ray crystallography.”

Claim Objections

The objection to claims 1-31 and 34 because of informality is withdrawn in view of the amendment filed 9/25/09.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-31 and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-12, 14-16, 19-20, 24-39, and 42-46 of US copending Application No. 10/790507 (allowed but not yet issued).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-31 and 34 of the instant application are drawn to a computer-based method for generating 3-D structural models of complex formation between a query ligand and a target macromolecule, the method comprising: a) providing a structural model of a query ligand and a structural model of a target macromolecule; wherein the structural model of the query ligand is based on data from X-ray crystallography or NMR spectroscopy, and the structural model of the target macromolecule is based on data from X-ray crystallography; b) identifying a substructure of the query ligand; c) identifying

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comparison ligands in a set of 3-D structural models that each share an identical substructure with the query ligand, wherein each 3-D structural model comprises a comparison ligand and a comparison macromolecule, and wherein the comparison macromolecule has structural features homologous to the target macromolecule of 20% or ~reater nucleic acid and/or amino acid homology; d) mapping spatial relationships between the substructure atoms of the query ligand and a comparison ligand identified in c) such that corresponding atoms are identified; e) assigning atomic coordinates to the corresponding atoms of the query ligand; f) generating and displaying one or more output models, each model comprising a 3-D structural model of the query ligand substructure and the target macromolecule, wherein the 3-D model of the query ligand substructure comprises the atomic coordinates of the query ligand from step (e).

Claims 1-4, 6-12, 14-16, 19-20, 24-39, and 42-46 of the copending application are drawn to a method for identifying potential ligands for protein macromolecular targets comprising: (1) providing a set of models, wherein each model comprises three-dimensional structural information for a ligand or a ligand:macromolecule protein complex, wherein each ligand comprises a plurality of atoms and a plurality of bonds, wherein each model is related to the other models of the set by a an amino acid homologous structural feature of 25% or greater for proteins or a structural homology between the ligands of at least 4-6 atoms in common; and wherein the structural information is derived from physical observation and/or computational inference; (2) mapping spatial relationships between the models such that the models are superimposed with respect to the homologous structural feature; (3) identifying one or more pairs of matching bonds between ligands of the

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set, wherein the matching bonds comprise a bond of a first ligand (B1) and a bond of a second ligand (B2) that are superimposed in step (2) such that (i) an atom at each end of the bond (B1) is within 1.8 angstrom of an atom at each end of the bond (B2), (ii) the bond (B1) and the corresponding bond (B2) are of the same bond order, and (iii) the bond (B1) and the corresponding bond (B2) are related by an angle of 30° or less; (4) selecting a plurality of subsets of atoms and/or bonds from each ligand; wherein each subset comprises a bond and/or, an atom connected to the matching bond as identified in (3); (5) generating and displaying output ligands, each output ligand comprising atoms and/or bonds of a first subset as selected in (4) and atoms and/or bonds of a second subset as selected in (4), wherein the first subset and the second subset comprise atoms and/or bonds derived from opposite ends of a matching bond as selected in (4).

It is clear that the instant claims are generic to the conflicting claims as macromolecules/targets are generic to proteins. Thus, 1-31 and 34 are anticipated by the conflicting claims of 10/790507.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to

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expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER

